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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,763	09/29/2006	Kazuwa Nakao	1254-0327PUS1	6725

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
04/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,763	NAKAO ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-22 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, drawn to a composition comprising a guanyl cyclase B (G—B) activator.

Group II, claims 11-17 and 22, drawn to a method for increasing a body height of an individual, comprising activating GC-B.

Group III, claims 18-21, drawn to a method of screening for an agent for increasing the body height comprising screening agents using the activity of GC-B as an indicator.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475 (B-D), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention would comprise comprises the first product (Group I; a composition comprising an activator of GC-B), and the first recited method of use of this product (Group II; a method that encompasses administration of a composition comprising an activator of GC-B).

However, the technical feature linking groups I and II appears to be that they each relate to a guanyl cyclase B (GC-B) activator; specifically, Group I is directed to a composition comprising said activator and Group II encompasses a method of using said activator. The specification and the claims teach that C-type natriuretic peptide (CNP) is a GC-B activator, including both the 22 and 53 amino acid forms (e.g., see claim 8). The recitations of "for increasing a body height" and "to be administered to an individual free from FGFR3 abnormality" in independent claim 1 is interpreted as an intended use for the claimed product and do not distinguish the claimed product from a product taught by the prior art. Thus, the claims of Group I encompass compositions comprising a C-type natriuretic peptide; and the claims of Group II encompass method of using a C-type natriuretic peptide. However, the prior art (Tanaka et al; U.S. Patent No. 6,034,231; published 3/7/00) teaches CNP-22 (22 amino acids) and CNP-53 (53 amino acids). See entire document; in particular, column 4, lines 30-46. Therefore, the prior art teaches a guanyl cyclase B (GC-B) activator that is the technical feature linking groups I and II.

Therefore, the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Furthermore, Group III is not part of the main invention because it is not part of either the first invention of the category first mentioned in the claims or the first recited invention of each of the other categories related thereto. Group III is a method of screening to identify agents using activity of GC-B as an indicator. Thus, Group III is a method of using test substances (agents) and GC-B, rather than being a method of use of composition comprising a known GC-B activator (Group I).

Elections of species in Group I or II

If Group I or II is elected, two elections of species are also required as follows:

(1) This application contains claims directed to more than one species of GC-B activator. The species are as follows: CNP-22 and CNP-53. The claims correspond to the species in the following manner:

1. Claims 1-6, 11-13 and 22 are generic.

2. Claims 7 and 14 are generic to any CNP peptide.

3. Claims 8-10 and 15-17 recite each species as a Markush-type group.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each CNP peptide is a structurally discrete peptide with a different sequence. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(2) This application contains claims directed to more than one species of patient. The species are as follows: (a) patient with short stature; and (b) individual other than a patient with short stature. The claims correspond to the species in the following manner:

1. Claims 1, 4-17 and 22 are generic.

2. Claim 2 corresponds to species (a).

3. Claim 3 corresponds to species (b).

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the recited patient populations are mutually exclusive (based on height) and thus lack a common structural feature. Lack of unity is shown because the treatment lacks a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(3) This application contains claims directed to more than one species of bones. The species are as follows: (a) cartilage bones; (b) femora; (c) tibiae; (d) radiuses; and (e) ulnae. The claims correspond to the species in the following manner:

1. Claims 1-3, 6-11, 14-17 and 22 are generic.

2. Claims 4 and 12 correspond to species (a).

3. Claims 5 and 13 recite each of species (b)-(e) as a Markush-type group.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each type of bone of the body is mutually exclusive from the other recited bones, and thus each bone is structurally discrete from the others. Lack of unity is shown because the bones lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647